K093895
p1/3

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (21CFR 807.92)

I. DATE PREPARED: 12/14/2009

MAY 20 2010

II. SUBMITTER:

Continuity Health Solutions
9304 Forest Lane, Suite N272
Dallas, TX 75243
Telephone: 866.517.3135
Fax: 214.553.8946

III. CONTACT PERSON:

Bryan Poteet, CEO
Telephone: 866.517.3135

IV. DEVICE NAME:

Trade/Proprietary Name:	ALLY™ Platform System
Common/Usual Name:	Telehealth System
Classification Name:	Physiological Signal Transmitters and Receivers

V. DEVICE CLASSIFICATION

Class II
CFR section: 870.2910 Physiological Signal Transmitters and Receivers
Product code: DRG
Panel: Cardiology

VI. PREDICATE DEVICES:

K090801
Electronic House Call System
Class II
Decision Date: 04/08/2009

K063612
Health hero Network
Class II
Decision Date: 12/29/2006

VII. SUBSTANTIAL EQUIVALENCE CONCLUSIONS:

Continuity Health Solutions concludes that the intended use for the Continuity Health Solutions ALLY™ Platform System is the same as that of the predicate devices, and that the technological characteristics demonstrate that they are equivalent to the predicate device. A comparison of the technological characteristics of the predicate and legally marketed devices available has been performed.

Thus, this premarket notification has demonstrated substantial equivalence.

VIII. DEVICE DESCRIPTION AND INTENDED USE:

Device Description:

ALLY™ is comprised of a home unit, legally marketed diagnostic peripherals, and a server. The home unit is a communications device that collects data from the diagnostic peripherals and. The patient in the home and transmits the data to the server over the home's existing telephone line or other identified method (existing high-speed connection in patients' home). The diagnostic peripherals comprise a wide range of legally marketed medical electronic devices capable of measuring patient parameters such as blood pressure, pulse rate, weight, etc. The server application responds to calls from the home units, collects the data, and then compares the data to preset thresholds. The healthcare practitioners and privileged users access the server through a secure website.

ALLY™ Care Portal

The ALLY™ Care Portal is intended to be used as an accessory to communication tools, such as the ALLY™ Home Appliance (RTX 337X). The ALLY™ Care Portal enables healthcare providers to request, receive, and review historical patient information. It is intended to be used in combination with a variety of external devices.

ALLY™ Home Appliance (RTX 337X)

The ALLY™ Home Appliance (RTX 337X) is for use in non-clinical settings (such as the home), as an accessory device that is intended to be a communication tool to enable healthcare providers to receive historical patient information. It is intended to be used in combination with a variety of external devices.

The ALLY™ Home Appliance (RTX 337X) serves as the remote communication link between compatible external devices, and the compatible healthcare facility at another location. The healthcare facility could be at a disease management center or with the healthcare/wellness provider or other out of hospital caregivers.

Intended Use:

The ALLY™ Platform System is a multi-platform medical device that is an accessory to approved 510k devices and is intended to be used as a means of receiving, storing, and transmitting patient biometric data including vital signs measurements. The ALLY™ Platform System is to be used upon prescription and under the supervision of an authorized healthcare provider.

The ALLY™ Platform System will send information to a remote database to be accessed by authorized clients, such as healthcare professionals or patient family members. Electronic data consisting of patient vital sign information, educational material, reminders, questionnaires, and patient responses are exchanged over a secure network connection. Information may be communicated via standard telephone lines, high speed internet connections, serial port interfaces, or Bluetooth® radio transceivers.

The ALLY™ Platform is a multi-platform application that is not intended to provide automated treatment decisions or perform data manipulation, diagnostics, or real-time alerts. The ALLY™ Platform is not intended to act as an emergency response system. All patient medical diagnosis and treatment are to be performed by an appropriate health care professional.

IX. SAFETY INFORMATION:

The ALLY™ Platform System has no patient contact and is utilized only by trained professionals. Trained professionals allow sufficient review to afford identification and intervention in the event of a malfunction have evaluated the output of the device. This will allow sufficient review to afford identification and intervention in the event of a malfunction.

X. CONCLUSION:

Continuity Health Solutions believes sufficient information is included to reach a determination of substantial equivalence. We conclude that the subject device is as safe and effective including the component and accessory devices.

As a result of this analysis and the risk reduction activities, and has reviewed the guidance document for the content of premarket submissions for software contained in medical device, we conclude that there is no software or hardware component in the ALLY™ Platform System that would be expected to result in injury or death to a patient due to a failure or latent design flaw. Thus, the "Level of Concern" of the ALLY™ Platform System product is "Moderate".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Continuity Health Solutions
c/o Mr. Bryan Poteet
CEO
9304 Forest Lane, Suite N272
Dallas, TX 75243

MAY 20 2010

Re: K093895
Trade/Device Name: ALLY™ Platform System
Regulatory Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: II (two)
Product Code: 74 DRG
Dated: April 13, 2010
Received: April 19, 2010

Dear Mr. Poteet:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

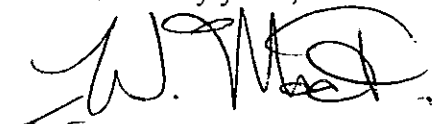
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K093895

510(k) Number (if known): N/A

Device Name: ALLY™ Platform System

Intended Use:

The ALLY™ Platform System is a multi-platform medical device that is an accessory to approved 510k devices and is intended to be used as a means of receiving, storing, and transmitting patient biometric data including vital signs measurements. The ALLY™ Platform System is to be used upon prescription and under the supervision of an authorized healthcare provider.

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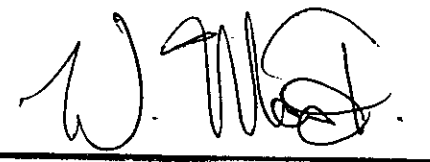
Prescription Use __X__ AND/OR Over the Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093895